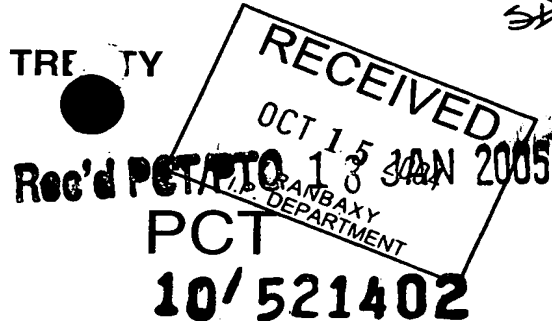


# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY



To:

RANBAXY LABORATORIES LIMITED  
c/o DESHMUKH, Jay. R.  
600 College Road East, Suite 2100  
Princeton, NJ 08540  
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing

(day/month/year)

11.10.2004

Applicant's or agent's file reference

RLL-274WO

**IMPORTANT NOTIFICATION**

International application No.

PCT/B 03/02838

International filing date (day/month/year)

17.07.2003

Priority date (day/month/year)

19.07.2002

Applicant

RANBAXY LABORATORIES LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/B/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-274WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA416)	
International application No. PCT/IB 03/02838	International filing date (day/month/year) 17.07.2003	Priority date (day/month/year) 19.07.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/4045		
Applicant RANBAXY LABORATORIES LIMITED		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 8 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of    sheets.

- This report contains indications relating to the following items:
  - I    ☒ Basis of the opinion
  - II   ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☒ Lack of unity of invention
  - V   ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  19.02.2004	Date of completion of this report  11.10.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Luangkhot, N  Telephone No. +49 89 2399-7857 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/B 03/02838

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

### Description, Pages

1-18 as originally filed

### Claims, Numbers

1-25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
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**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 2,18-22, 28-30, 52-54 with respect of industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 52-54 with respect of industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):  
☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
☒ no international search report has been established for the said claims Nos. 2,18-22, 28-30

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the Standard.  
☐ the computer readable form has not been furnished or does not comply with the Standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.  
☐ paid additional fees.  
☐ paid additional fees under protest.  
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/B 03/02838**

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- ☐ all parts.
- ☒ the parts relating to claims Nos. 1,3-17,23,46-49,52-54 .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1,3-17,23,46-49,52-54
Inventive step (IS)	Yes: Claims	
	No: Claims	1,3-17,23,46-49,52-54
Industrial applicability (IA)	Yes: Claims	1,3-17,23,46-49
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item I**

**Basis of the opinion**

Claims 2, 18-22 and 28-30 do not meet the requirement of Art.6 PCT for lack of clarity because they are directed to a subject-matter (process comprising further the step of polishing the tablet with wax) which is **in contradiction with** the subject-matter of their independent claims (process of producing uncoated tablet), namely inventions 1 and 3. The step of wax polishing in claims 2, 18-22 and 28-30 belongs in fact to the subject-matter of invention 2, which can not be examined in the PCT phase because a search report has not been drawn up for this subject-matter. Therefore even if they depend prima facie on claims 1 or 24, they will not be considered **as long as their corresponding independent claims are not novel and not inventive**.

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 52-54 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item IV**

**Lack of unity of invention**

This International Examining Authority (IEA) found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1, 3-17, 23, 46-49, 52-54 (2, 18-22)

Process for manufacturing an **uncoated** sumatriptan tablet comprising:

1/ manufacturing **granules** of sumatriptan with diluents or binders

2/ mixing the obtained granules with other excipients in order to obtain a mixture or an extragranular portion

3/ compressing the product of step 2 in order to form a tablet

2. Claims: 37-45, 50-51

Process for manufacturing a **coated** sumatriptan dosage form comprising **wax polishing** the dosage form

3. Claims: 24-27, 31-36 (28-30)

Process for manufacturing a sumatriptan tablet comprising:

1/ spraying a solution or suspension of sumatriptan onto **inert cores**, and optionally further spraying a solution of binders or diluents onto the cores having the first layer (claims 26-27)

2/ mixing the product of step 1 with other excipients in order to form a mixture

3/ compressing the mixture to form a tablet

The problem underlying the present application can be seen as providing a sumatriptan tablet formulation wherein the bad taste of sumatriptan is masked.

3 distinguishable solutions were identified in this application as follows:

1/ Process as described in claims 1, 3-17, 23, 46-49, 52-54, wherein **granules of sumatriptan** are prepared at first and the tablet is uncoated.

2/ Process as described in claims 37-44, 45, 50-51, wherein a **wax polishing** coats the dosage form.

3/ Process as described in claims 24-25, 26-27, 31-36, wherein an **inert core with a coating layer containing sumatriptan** is prepared at first.

A linking concept between invention 2 and inventions 1 or 3 is missing a priori. For further information see above **"Re Item I Basis of the opinion"**.

The common concept linking inventions 1 and 3 can be seen as the active ingredient is sheathed by excipients which form a surrounding body of compressed powder or granular material.

Example 6 of D1 and Example 1 of D2 describe a process of manufacturing a tablet core which seems to be exactly the same as described in Example 1 of present application. Furthermore the amounts of the diverse ingredients used are also similar to those of present application.

Therefore as Example 1 of present application illustrates the first invention, the subject-matter of independent claims 1, 46 and 52 and the common concept between invention 1 and 3 is consequently not novel and inventive.

Example 1 of D3 (see also claims 1-4, 12-13) describes a process of manufacturing an uncoated tablet wherein granules of eletriptan, a derivative of sumatriptan, are surrounded by excipients and the taste of the drug is undetectable (p.11 L.14-15). This teaching can be applied to sumatriptan. Therefore in view of D3 the common concept between invention 1 and 3 is not inventive.

As the IEA is unable to identify any common concept between the 3 groups of inventions which is novel and inventive, no unifying concept can be acknowledged in present application which contains 3 inventions.

As a search report has been only drawn up for the first invention, this one will be herein examined.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1) The documents cited in the International Search Report (ISR) were numbered respectively from D1-D7; this numbering results from the citation order in the ISR and will be used for the procedure. Unless otherwise specified, the cited passages of each document in the ISR will be considered.  
For the present examination it would be assumed that the priority date of present application is valid so that the P-document D4 and E-document D5 which fall under the definition of Rule 70.10 PCT are not considered for the PCT phase.
- 2) **Novelty and inventive step according to Art. 33(2) and 33(3) PCT**
  - 2a) Example 6 of D1 and Example 1 of D2 describe a process of manufacturing a sumatriptan uncoated tablet which seems to be exactly the same as described in Example 1 of present application. Furthermore the amounts of the diverse ingredients used are also similar to those of present application. The uncoated tablets of D1 and D2 are further coated with a sugar or HPMC film.  
If the way of manufacturing the uncoated tablets of D1 or D2 is the same as present application it is then to be expected that the uncoated tablet of D1 or D2 masks the unpleasant taste of sumatriptan.

The disclosure of D1-D2 anticipates the subject-matter of independent claims 1, 46

and 52 which is not novel.

This applies to dependent claims 3-17,23,47-49 and 51-52 because they do not contain any feature that could confer novelty to the subject-matter of the first invention.

- 2b) Even if applicant was able to overcome the novelty objection, the subject-matter of the first invention does not involve an inventive step:

Example 1 of D3 (see also claims 1-4,12-13) describes a process of manufacturing an uncoated tablet wherein granules of elepriptan, a derivative of sumatriptan, are surrounded by excipients and the taste of the drug is undetectable (p.11 L.14-15). The skilled man, willing to produce a sumatriptan tablet wherein the bad taste is masked, will use the teaching of D3 and arrive at the claimed tablet and process of present application. Moreover, there is no reason to believe that this teaching cannot be applied to sumatriptan.

Therefore the subject-matter of independent claims 1,46 and 52 is not inventive in the light of D3.

This applies to dependent claims 3-17,23,47-49 and 51-52 because they do not contain any feature that could confer inventive step to the subject-matter of the first invention.

- 3) For the assessment of the present claims 52-54 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a composition in medical treatment, but may allow, however, claims to a known composition for first use in medical treatment and the use of such a composition for the manufacture of a medicament for a new medical treatment.
- 4) Contrary to the requirements of Rule 5.1(a)(ii) PCT, it seems that the relevant background art disclosed in the document D3 is not mentioned in the description, nor are this document identified therein.